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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,869	06/14/2006	Bernd Hansen	51336	5951
ROYLANCE, ABRAMS, BERDO & GOODMAN, L.L.P. 1300 19TH STREET, N.W.			EXAMINER	
			TRUONG, THANH K	
SUITE 600 WASHINGTON,, DC 20036			ART UNIT	PAPER NUMBER
W.1.51111 (G.1.6	1,,, 20 2000		3721	
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			MAIL DATE	DELIVERY MODE
			01/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		$\mathcal{O}_{\mathcal{K}}$				
	Application No.	Applicant(s)				
	10/582,869	HANSEN, BERND				
Office Action Summary	Examiner	Art Unit				
	Thanh K. Truong	3721				
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with	the correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.15 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period was a failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICA 36(a). In no event, however, may a repl will apply and will expire SIX (6) MONTH e, cause the application to become ABAN	ATION.  ly be timely filed  IS from the mailing date of this communication.  NDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 14 Ju	<u>une 2006</u> .					
a) This action is <b>FINAL</b> . 2b) This action is non-final.						
3) Since this application is in condition for allowar	nce except for formal matter	s, prosecution as to the merits is				
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 1	I1, 453 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-11</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-11</u> is/are rejected.						
7) Claim(s) is/are objected to.	7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/o	r election requirement.					
Application Papers						
9) The specification is objected to by the Examine	er.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the	drawing(s) be held in abeyance	:. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correct	tion is required if the drawing(s)	is objected to. See 37 CFR 1.121(d).				
11)☐ The oath or declaration is objected to by the Ex	caminer. Note the attached C	Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of:	priority under 35 U.S.C. § 1	19(a)-(d) or (f).				
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
) Notice of References Cited (PTO-892)	,	nmary (PTO-413) Mail Date				
Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08)		rmal Patent Application				
Paper No(s)/Mail Date <u>6-14-06</u> .  6) Other:						

Application/Control Number:

10/582,869 Art Unit: 3721

### **DETAILED ACTION**

## Specification

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

## Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2, 3 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim 3, the phrase "under a specified excess pressure" is vague and indefinite, because it is unclear what is the specified excess pressure? In other words, the quantity of the specified excess pressure has to be expressly recited.

Claim 9, the phrase "may be closed" (line 3) is vague and indefinite, because it implies that it may closed or may not closed, and thus it is unclear which is being claimed. Similarly, the phrase "may be moved" (line 6 and line 14) is vague and indefinite.

Claim 9 recites the limitation "the sterile filling space" in line 11. There is insufficient antecedent basis for this limitation in the claim.

4. <u>Examiner's note</u>: reference US 2004/0065983 A1 is being use as an English translation for the (DE 10063282 C2).

Art Unit: 3721

## Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansen et al. (DE 10063282 C2).

Hansen et al. discloses an apparatus (claim 1) and a method (claim 9) comprising: at least one tube (3) of softened plastic material is extruded into an opened mold (6), the tube is closed at its projecting end when the mold (6) is closed to form the bottom of the container, the tube is separated above the mold by means of a separating element (21) to form a filler opening (15), and the mold is moved with the tube having the filler opening into a filling position in which the container, after it has been formed by generation in the mold of a pressure gradient acting on the tube and expanding it, is filled and then sealed (figures 1-2), the filler opening of the tube being covered by a sterile barrier (23) at least from the time of its formation to that of filling of the respective container, wherein by means of the sterile barrier (23) at least one sterile medium (it is construed that the heated plate heats the surrounding air, and the hot air is the sterile medium) is moved in the direction of the filler opening (15) by means of a media delivery device (23).

Hansen et al. further discloses:

Art Unit: 3721

Regarding claim 5, the sterile barrier is configured as a plate-shaped cover element (23) which, after separation of the tube, covers the filler opening and provides it with a sterile medium until filling of the container is undertaken after its expansion below the sterile filling space (as mention above, it is construed that heated air is the sterile medium).

Regarding claim 6, the cover element (23) moves together with the separating element (21) for separation of the plastic tube.

Regarding claims 7 and 10, wherein the container is rinsed by or partly filled with the respective medium by means of the media delivery device (23), by way of the filler opening (as mention above, it is construed that heated air is the sterile medium).

Regarding claim 8, wherein the sterile barrier and/or the sterile medium are heatable, by preference to a temperature higher than 120 degrees C, by preference to a temperature situated within the range of 150 to 200 degrees C (see claim 4).

## Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. Claims 2-4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen et al. (DE 10063282 C2) in view of Zelina et al. (US 2002/0159915 A1).

**Art Unit: 3721** 

As discussed above, Hansen et al. discloses the claimed invention, but it does not expressly disclose that the media is hydrogen peroxide as recited in claim 2, and a suction device in the form of a vacuum device as in claims 4 and 11.

Zelina et al. discloses an apparatus and a method in which the sterile medium is hydrogen peroxide ([0035] page 2) and a suction device in the form of a vacuum device (112 is used (figure 1) to provide means to sterilize and decontamination the sterile filling space (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified Hansen et al. by incorporating the use of sterile medium and vacuum device as taught by Zelina et al. to provide means for sterilizing and decontamination the sterile filling space to achieve the condition as recited in claims 2-4 and 11.

### Conclusion

- 9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thanh K. Truong whose telephone number is 571-272-4472. The examiner can normally be reached on Mon-Thru 8:00AM 6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada can be reached on 571-272-4467. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10/582,869

Art Unit: 3721

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

tkt

December 29, 2007.

THANH K. TRUONG
PRIMARY EXAMINER

TECHNOLOGY CENTER 3700